

### **REMARKS**

Claims 1-4, 7, 8, 11-20 and 52 -55 are currently pending in this application. Claim 1 has been amended to delete the recitation that the polymer is sodium acrylate, and this recitation has been incorporated into new claim 56. No new matter has been added by way of this amendment.

After entry of this amendment, claims 1-4, 7, 8, 11-20 and 52 -56 will be pending in this application. Applicants respectfully request reconsideration of pending claims 1-4, 7, 8, 11-20 and 52-56.

Applicants acknowledge with gratitude the Examiner's withdrawal of the double patenting rejections over each of U.S. Patent Nos. 6,335,028; 6,660,301; and 6,790,456, as well as the rejections under 35 U.S.C. § 112 regarding enablement.

#### **I. Rejection Under 35 U.S.C. § 112, First Paragraph**

Claim 55 has been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement (Office Action, pages 2-3).

Applicants respectfully traverse this ground of rejection.

The Examiner opines that the recitation that "the polymer is not cross-linked" lacks support in the application as originally filed.

Respectfully, Applicants direct the Examiner's attention to the specification, which states that "[t]he present invention relates to tissue bulking...using injectable compositions comprising swellable hydrophilic microspheres" (page 1, lines 5-7) and:

The microspheres of the invention are highly water absorbing and capable of swelling to many times of their original sizes under certain conditions. The microspheres of the present invention generally comprise crosslinked polymers. Preferably, the microspheres comprise sodium acrylate polymer, acrylamide polymer, acrylamide derivative polymer or copolymer, sodium acrylate and vinyl alcohol copolymer, vinyl acetate and acrylic

acid ester copolymer, vinyl acetate and methyl maleate copolymer, isobutylene-maleic anhydride crosslinked copolymer, starch-acrylonitrile graft copolymer, crosslinked sodium polyacrylate polymer, crosslinked polyethylene oxide, or mixtures thereof.

(page 7, lines 2-4; emphasis added). Thus, while crosslinked polymers may be a preferred embodiment, the microspheres of the present invention may or may not comprise crosslinked polymers.

Thus, Applicants submit that the claim 55 complies with all the requirements of 35 U.S.C. § 112, first paragraph. Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

## **II. Rejection Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-4, 7-8, 11-20 and 52-55 have been rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite (Office Action, pages 3-4).

Applicants respectfully traverse this ground of rejection.

First, the Examiner opines that the term “high” in claim 1 is a relative term which renders the claim indefinite.

Applicants note that the term “high” recited in the claims is used in the context of the phrase “high water absorbing polymer,” which is explicitly defined in the specification

“High water absorbing polymers” as used in the present invention refers to polymers that can absorb at least 5% of water by weight or that are capable of increasing their dry weight to about 20 times of their original weight.

(page 10, lines 25-27). Thus, Applicants respectfully submit that the term “high,” taken in context of the phrase “high water absorbing polymer,” is definite.

Second, the Examiner opines that because claim 1 recites acrylate polymers, as well as sodium acrylate polymers, the claim is indefinite.

While the Applicants disagree with the Examiner's assertion, and solely in an effort to advance prosecution of this application, Applicants have amended claim 1 to delete the recitation that the polymer is sodium acrylate. New dependent claim 56 has been added, which recites the composition of claim 1, wherein the polymer is a sodium acrylate polymer or copolymer thereof.

Thus, Applicants respectfully submit that each of the pending claims complies with the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

### **III. Rejection Under 35 U.S.C. § 102(b)**

Claims 1-4, 7, 8, 11-20, 52 and 54-55 have been rejected under 35 U.S.C. § 102 as allegedly being anticipated by Boschetti *et al.* (U.S. Patent No. 5,635,215) ("Boschetti") (Office Action, page 4).

Applicants respectfully traverse this ground of rejection.

The Examiner opines that Boschetti "teaches the spherical particles herein and suspension composition comprising the same used for injection" (Office Action page 4).

As the Examiner appreciates, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added).

Boschetti does not disclose each and every element recited in independent claim 1. Nowhere does Boschetti disclose swellable microspheres, *much less* a swellable microsphere comprising a high water absorbing polymer, as recited in independent claim 1. As those skilled in the art are aware, not all hydrophilic acrylic polymers are swellable and/or high water absorbing polymers. As such, Boschetti does not disclose each and every element

recited in independent claim 1, and, as such, cannot anticipate the claimed invention.

For at least these reasons, Applicants respectfully submit that independent claim 1 is novel of Boschetti. Similarly, each of claims 2-4, 7, 8, 11-20 and 52-56, which depend either directly or indirectly on independent claim 1, and thus incorporate all the limitations thereof, is also novel over Boschetti. According reconsideration and withdrawal of this ground of rejection is respectfully requested.

#### **IV. Rejection Under 35 U.S.C. § 103**

##### **A. Claims 1-4, 7, 8, 11-20, 52 and 54-55**

Claims 1-4, 7, 8, 11-20, 52 and 54-55 have been rejected under 35 U.S.C. § 103 as allegedly being obvious over Boschetti (U.S. Patent No. 5,635,215) (Office Action, pages 5-7).

Applicants respectfully traverse this ground of rejection.

The Examiner opines that Boschetti “teaches the spherical particles herein and suspension [*sic*] composition comprising the same used for injection” (Office Action, page 5). The Examiner also opines that “it would have been prima facie obvious to a person of ordinary skill in the art...to adjust the particle size within the disclosed range so that the composition would be suitable for injection with any needle required in the method” (*Id.* at pages 5-6).

However, while the Examiner appears to be focusing on the size ranges disclosed in Boschetti as the basis for the obviousness rejection, the Examiner has not provided any evidence that Boschetti discloses swellable microspheres comprising a high water absorbing polymer, as recited in the claims.

Where applicable, the findings should clearly articulate which portions of the reference support any rejection. Explicit findings on motivation or suggestion to select the claimed invention should also be articulated in order to support a 35 USC 103 ground of rejection. *Dillon*, 919 F.2d at 693, 16 USPQ2d at 1901; *In re Mills*,

916 F.2d 680, 683, 16 USPQ2d 1430, 1433 (Fed. Cir. 1990).  
Conclusory statements of similarity or motivation, without any  
articulated rationale or evidentiary support, do not constitute  
sufficient factual findings.

Manual of Patent Examination Procedure § 2144.08 (emphasis added).

While it is true that Boschetti *generally* teaches microspheres comprising a hydrophilic acrylic copolymer for vascular embolization, the reference does not teach or make obvious the claimed swellable microspheres comprising a high water absorbing polymer. *See, e.g., Ex parte Obukowicz*, 27 USPQ2d 1063, 1065 (Bd. Pat. App. & Int’f 1992) (prior art which provides only general guidance and is not specific as to the particular form of the claimed invention and how to achieve it does not render the invention unpatentably obvious).

The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) (‘The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.’); *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) (Federal Circuit has ‘decline[d] to extract from *Merck & Co. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989)] the rule that... regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it.’). *See also In re Deuel*, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995).

As discussed above, Boschetti does not disclose *any* swellable microspheres...*much less* swellable microspheres comprising a high water absorbing polymer, as recited in the claims. None of the microspheres disclosed in Examples 1-21 of Boschetti are swellable microspheres comprising a high water absorbing polymer, nor are such microspheres suggested by Boschetti. As those skilled in the art are aware, not all hydrophilic, acrylic polymers are swellable and/or high water absorbing. Thus, Boschetti does not disclose or suggest any swellable microspheres comprising a high water absorbing polymer, as recited in the claims.

Further, because the microspheres disclosed in Boschetti (see Examples 1-21) were sufficient for vascular embolization, one skilled in the art would have had no motivation whatsoever to use the claimed swellable microspheres comprising a high water absorbing polymer for vascular embolization *much less* for tissue bulking, which is a completely unrelated field.

Thus, for at least these reasons, Applicants submit that Boschetti does not render any of 1-4, 7, 8, 11-20 and 52-56. Accordingly, reconsideration and withdrawal of this ground of rejection is respectfully requested.

**B. Claim 53**

Claim 53 was also rejected as allegedly being obvious over Boschetti in view of Tahara (U.S. Patent No. 5,298,570) ("Tahara").

Applicants respectfully traverse this ground of rejection

For the reasons discussed above, Applicants submit that Boschetti does not render obvious the claimed microspheres. While it is true that Boschetti *generally* teaches microspheres comprising a hydrophilic acrylic copolymer for vascular embolization, the reference does not teach or make obvious the claimed swellable microspheres comprising a high water absorbing polymer. See, e.g., *Ex parte Obukowicz*, 27 USPQ2d at 1065; *In re Baird*, 16 F.3d at 382; *In re Deuel*, 51 F.3d at 1559. That is, nowhere does Boschetti disclose or suggest swellable microspheres, *much less* a swellable microsphere comprising a high water absorbing polymer, as recited in the claims. As those skilled in the art are aware, not all hydrophilic acrylic polymers are swellable and/or high water absorbing polymers.

Furthermore, contrary to the Examiner's assertions, Tahara does not supply the disclosure of Boschetti. Tahara is cited as teaching sodium acrylate / vinyl alcohol copolymers. The Examiner asserts that it therefore would have been *prima facie* obvious to a person of skill in the art to use the sodium acrylate / vinyl alcohol copolymers as the hydrophilic polymer, and the alleged motivation comes from the fact that this copolymer was

known. The Examiner also cites *Ex parte Winters* 11 USPQ 2d 1387, 1388 for the proposition that “[t]he employment of the copolymer is seen to be a selection from amongst equally suitable material and as such obvious” (Office Action, page 7).

However, when read in context, *Winter* actually states that “[some] compounds, falling within the scope of a prior art genus, are unpatentable in the absence of a showing of unexpectedly superior results” (*Winter* at 1388 (citing *In re Lemin*, 332 F.2d 838, 141 (CCPA 1964)). Here, Applicants have disclosed a number of advantages of the claimed swellable microspheres over prior art microspheres in the specification, *e.g.*, at page 13, lines 3-16.

For at least these reasons, Applicants submit that claim 53 (as well as new claim 56) is non-obvious over Boschetti in view of Tahara. As such, Applicants respectfully request that this rejection be reconsidered and withdrawn.

## V. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully submit that this application is now in condition for immediate allowance. *If the Examiner disagrees, Applicants respectfully request that the Examiner call the undersigned at the number listed below.*

A Petition for a One (1) Month Extension of Time is submitted herewith, with provisions for the required fee, which extends the response period from July 10, 2006 to August 10, 2006. The Petition further authorizes the PTO to charge the one month extension fee of \$60 to Jones Day Deposit Account No. 50-3013, which reflects Applicant’s Small Entity Status. As Amendment Fee Transmittal Sheet is submitted herewith, which authorizes the \$25 extra claim fee to be deducted from the same Deposit Account. A Notice of Appeal is also submitted herewith, with provisions for the required fee.

Applicants believe no other fees are due in connection with this response. However, if there are any other fees due, please charge them to Deposit Account 50-3013. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above or in the

Petition filed concurrently herewith, such an extension is requested and the fee should be charged to our Deposit Account. Also, please charge any fees underpaid or credit any fees overpaid to the same Deposit Account.

Respectfully submitted,



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